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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,329

01/29/2004

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EXAMINER

BERHANU, ETSUB D

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/766,329	<b>Applicant(s)</b> SHANI ET AL.	
	<b>Examiner</b> ETSUB D. BERHANU	<b>Art Unit</b> 3768	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.                                                          | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11, 12 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "the measured capillary filling time" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claim 12 recites the limitation "the capillary filling time" in line 2 and lines 6-7. There is insufficient antecedent basis for this limitation in the claim. Claim 11 recites the limitation "the capillary filling time" in line 5. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 5 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 5 improperly recites human tissue as part of the claimed invention. It is suggested that the Applicant amend the claim to include the phrase "adapted to be placed on the skin area" or "capable of being placed on the skin area" in order to remove human tissue from the invention.

### ***Double Patenting***

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ...

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may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 45, 48 and 49 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 34, 35 and 36, respectively, of prior U.S. Patent No. 6,685,635. This is a double patenting rejection.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-19, 21-24, 32-37, 46 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-14, 16-28, 30-34 of U.S. Patent No. 6,685,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the US Patent disclose all of the details of the claims of the current invention, except for the details of what type of light is used to illuminate the skin. It is well known in the art to use a light source to illuminate skin and a photodetector to intercept light reflected from the illuminated surface. Further, it would be obvious to one of ordinary skill in the art to determine which type of light, either modulated or

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non-modulated, would produce the best results for a measurement to be performed using the apparatus and method disclosed in the claims of the current invention.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schriger (cited by Applicant) discloses a method of determining whether a patient is suffering from a pre-shock, shock or shock-related condition wherein the method is based on a capillary filling time. The method utilizes a constant pressure applied to the skin during a constant period of time, wherein the applied pressure causes the skin to change color, and measures the time it takes for the color of the skin to return to its baseline (original) color using a digital stopwatch. Schriger fails to disclose a color sensor means to illuminate the skin area or to intercept light reflected from the illuminated skin area. Oman et al.'554 (cited by Applicant) discloses an apparatus and method for indicating the onset of shock by measuring the color of skin using a light source, a photodetector and a temperature sensor. Oman et al.'554 fails to disclose indicating the onset of shock wherein a capillary filling time is utilized. None of the prior art teaches or suggests, either alone or in combination, an instrument or method comprising either: means responsive to a signal before a pressure is applied to skin wherein the means establishes a reference base indicating a baseline color of the skin, and means capable of relating a capillary filling time measurement to a shock indication after pressure is applied to the skin area to cause a color change in the skin area, and a time is measured from when the depressed skin is at its maximum blanching value of white to when the skin reaches its baseline color once the pressure has been released; means for filtering a signal to obtain a base-line color measurement and determining a filling time of blood vessels by comparing a current color of the skin area with the base-line measurement; a transducer capable of applying pressure on an illuminated skin area and obtaining an amplitude of a signal, the amplitude being proportional to an amplitude of another measured signal, and wherein the amplitude also corresponds to a

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maximum whitening value of the skin area; or means for acquiring image data corresponding to the color of a skin area when essentially no pressure is applied to the skin area, wherein the image data acquired is used to obtain a base-line color measurement that is compared to a color of the skin area when depressed, the comparison being used to determine a filling time of blood vessels in the skin area after releasing the pressure, in combination with the other claimed elements or steps.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

EDB